

## SJ-EXHIBIT 6

U.S. Department of Justice  
Drug Enforcement Administration

## REPORT OF INVESTIGATION

Page 1 of 14

1. Program Code	2. Cross File	Related Files	3. File No. [REDACTED]	4. G-DEP Identifier
5. By: Lewis D Colosimo, DI At: Pittsburgh DO	<input type="checkbox"/>		6. File Title Approval of Application - Type B (225/225A)	
7. <input type="checkbox"/> Closed <input checked="" type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:	<input type="checkbox"/>		8. Date Prepared 01-11-2016	
9. Other Officers: GS Kurt Dittmer, RPS Patricia Robison, IA Kayla Solonichne				
10. Report Re: GIANT EAGLE RX DISTRIBUTION CENTER, 2500 Lovi Road, Freedom, PA 15042, Control Number W15103194F [REDACTED]				

**SYNOPSIS**

On November 25, 2015, a representative from GIANT EAGLE, INC. submitted an application for registration as a distributor (Schedules 2-5) for GIANT EAGLE RX DISTRIBUTION CENTER (GERXDC), 2500 Lovi Road, Freedom, PA 15042, Control Number W15103194F. In December 2015, investigators from the Pittsburgh District Office met with GERXDC management and conducted a complete pre-registrant investigation. The application for GERXDC was approved on January 8, 2016; GERXDC was assigned DEA Registration Number RG0491047.

**SUBJECT FIRM'S BACKGROUND**

In October 2009, the Pittsburgh District Office approved HBC SERVICE COMPANY (hereinafter HBC) as a distributor of Schedules 3-5 controlled substances at 601 A Meadowlands Boulevard, Washington, PA 15301, DEA# RH0389773. HBC, a division of GIANT EAGLE, INC., has since distributed Schedule 3-5 controlled substances to over 200 pharmacies owned by GIANT EAGLE, INC. located in Pennsylvania, Ohio, West Virginia, Maryland, and Indiana. HBC has been the subject of three in-depth cyclic investigations by the Pittsburgh D.O: [REDACTED], [REDACTED], and [REDACTED], none of which resulted in any administrative actions.

11. Distribution: Division	12. Signature (Agent)  Lewis D Colosimo, DI	13. Date 01-11-2016
District	14. Approved (Name and Title) /s/ Kurt G Dittmer, GS	15. Date 01-12-2016
Other [REDACTED]		

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DEFENDANT'S DEPOSITION  
EXHIBIT  
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Colosimo

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HBC is also registered with DEA as a distributor of List I chemicals under DEA Registration Number 001753HVY. The subject firm was the subject of in-depth chemical regulatory/cyclic investigations in 2002 [REDACTED], 2004 [REDACTED], 2008 [REDACTED], and 2014 [REDACTED]. No violations were uncovered during these investigations.

Over the past several years, MCKESSON DRUG, a distributor in New Castle, PA, has been the primary supplier of Schedule 2 controlled substances to the Giant Eagle pharmacies. In the summer of 2015, Richard Shaheen, Pharmacy Investigator for GIANT EAGLE, INC., informed Kurt Dittmer, Diversion Group Supervisor, and John Conlon, Diversion Investigator, that GIANT EAGLE, INC. was considering adding a cage and vault to an existing warehouse owned by GIANT EAGLE in Freedom, PA, where they would be able to distribute Schedules 2-5 controlled substances to Giant Eagle Pharmacies; Shaheen said that when this new location was approved by DEA, controlled substances would no longer be dispensed at the HBC warehouse in Washington, PA. GS Dittmer and DI Conlon met with Shaheen and advised him of the requirements for a cage and vault as outlined in 21 CFR 1301.72. Shaheen indicated that an application for DEA registration would be submitted when the cage and vault were near completion.

On November 25, 2015, Deborah Elms submitted an application for registration as a distributor (Schedules 2-5) for GIANT EAGLE RX DISTRIBUTION CENTER (GERXDC), 2500 Lovi Road, Freedom, PA 15042, Control Number W15103194F. On October 1, 2015, GERXDC was granted a license with the Pennsylvania Department of Health as a Distributor, Certificate Number 3000009407, expiration date October 31, 2016. (**Attachment 1**)

#### **PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES**

On December 14, 2015, GS Dittmer, DI Lewis Colosimo, Kayla Solonichne, Investigative Assistant, and Patricia Robison, Registration Program Specialist, conducted an onsite pre-registrant investigation at the GERXDC. During this investigation, they met with the following representatives from GIANT EAGLE, INC as listed on the attached sign-in sheet (**Attachment 2**):

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George Chunderlik, Manager, Pharmacy Compliance  
Joseph Millward, Senior Manager, Pharmacy Quality and Compliance  
Walter Durr, Senior Manager of Manufacturing and Operations  
Richard Shaheen, Pharmacy Investigator  
Phil Raub, Pharmacy Analyst  
David Hubsch, Distribution Support  
Christy Hart, RX Lead  
Adam Zakin, Senior Director of Pharmacy Administration

Though DI Colosimo informed all present that GERXDC was responsible for complying with 21 CFR Part 1300 to end, DI Colosimo provided all present with CFR references particularly relevant to distributors - ARCOS reporting, records, CSOS, Cage/Vault requirements, suspicious orders, thefts/losses, and confirming the DEA registration number for customers (**Attachment 3**). Each of these items was thoroughly reviewed with GERXDC personnel; information provided by GERXDC personnel regarding these and other subjects is detailed throughout the body of this report. During this meeting, DI Colosimo was provided with a number of GERXDC written policies and standard operating procedures which will be cited throughout this report.

On December 18, 2015, Lori Wiechelt, Senior Corporate Counsel for GIANT EAGLE, INC., provided DI Colosimo with correspondence listing all GERXDC personnel who will have access to the firm's cage and vault (**Attachment 4**):

Name	Social Security Number	Date of Birth
Walter Durr	[REDACTED]	[REDACTED]
Mat Hubert	[REDACTED]	[REDACTED]
Christy Hart	[REDACTED]	[REDACTED]
Dave Hubsch	[REDACTED]	[REDACTED]
Larry Colonello	[REDACTED]	[REDACTED]
Jason Zetts	[REDACTED]	[REDACTED]

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NADDIS queries regarding these individuals did not reveal any negative information.

### RECORD KEEPING

Through their experience at HBC, GERXDC personnel present for the meeting expressed their familiarity with record keeping requirements pertaining to the handling of controlled substances.

As noted above, prior cyclic investigations conducted at HBC have not resulted in any administrative actions. HBC was the subject of its first regulatory inspection/cyclic investigation in May 2011, and documented under DEA file number ██████████. The result of this investigation revealed minor recordkeeping violations (an overage due to computer software malfunction). This issue was resolved on-site.

GERXDC will retain all inventories and records of all transactions regarding the receipt and distribution of controlled substances for a period of three (3) years. GERXDC management informed DEA that all documents required by DEA to complete an in-depth cyclic investigation at GERXDC will be maintained on-site and will be readily retrievable.

GERXDC will distribute controlled substances solely to Giant Eagle Pharmacies. Customers will generate orders for Schedule 2 controlled substances through CSOS; Schedule 3-5 orders will be generated by the pharmacy's dispensing system.

### ARCOS

Though the individual responsible for ARCOS reporting, Kris Remas, was not present at this meeting, Adam Zakin indicated that Remas is aware of ARCOS requirement through her current position at HBC. A review of HBC's ARCOS history revealed all required reports were filed in a timely manner, with no delinquencies.

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### CSOS

Joseph Millward, Senior Manager, Pharmacy Quality and Compliance, said he was aware of CSOS (Controlled Substance Ordering System) requirements as outlined in 21 CFR Part 1311 Subpart B. He said that CSOS certification would be applied for upon the issuance of a DEA Registration Number.

### THEFT/LOSS

GERXDC personnel were advised of the requirement to notify DEA upon discovery of any theft or significant loss of a controlled substance. The GERXDC policy regarding thefts/losses, including inbound and outbound in-transit losses, is detailed in the STORAGE section of this report. A review of DEA's Theft/Loss database revealed HBC filed four DEA Form 106s (Report of Theft or Loss of Controlled Substances) since they were approved by DEA as a distributor in 2009: one loss was attributed to employee pilferage (his employment was terminated); three were described as in-transit losses. HBC appropriately documented on each of the forms security measures they took to prevent or limit future thefts/losses.

### SECURITY

GERXDC, located in an industrial park (Tri-County Commerce Park) in New Sewickley Township, occupies 13,515 square feet of a 210,000 square foot building constructed of poured reinforced concrete, steel, and brick. Other occupants of the building are limited to Giant Eagle entities such as the Giant Eagle Pharmacy (Central Fill, no walk-in business - DEA Number FG5586447), Giant Eagle fresh foods department, and Giant Eagle storage of health and beauty supplies. Operating hours for the GERXDC will be 5:00 a.m. to 12:30 a.m., Monday through Saturday. GERXDC maintains sufficient external lighting to identify delivery drivers and trucks, as well as to light areas that are under 24 hour video surveillance.

Access to the GERXDC is limited to identifiable employees who have direct, day-to-day functions within the GERXDC (i.e. receiving, replenishment, stocking, and selection). Key FOBs/badges are required to enter and exit the GERXDC. The Key FOBs/badges also allow GERXDC management to restrict unauthorized access into the GERSDX, and further limit access to the

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firm's cage and vault.

All employees with access to the firm's cage and vault and those involved in handling Schedule 2-5 controlled substances must undergo the required background checks associated with the following 21 CFR sites: 1301.76, 1301.90, 1301.92, and 1301.93.

The cage and vault will be locked when not in use. It will be permissible for the cage to be unlocked when it is in use as long as it is being monitored by an authorized member of the GERXDC operation's management team. Keys to unlock the cage and vault will be in the possession of the operation's management.

GERXDC has multiple video surveillance cameras in the cage/vault, providing adequate monitoring of any employee movement while in the cage/vault.

Any visitor to GERXDC must first sign the Visitor's Log upon entering the facility. A visitor's admittance into the facility is permitted only when the visitor is accompanied by a member of the GERXDC operation's management team. The visitor must be supervised at all times. At no time will a visitor be unsupervised while in the GERXDC production area where items, including controlled substances, are store, received, or distributed.

In the event of a power loss, the GERXDC has an industrial-grade backup generator to ensure continuing operations.

The firm's electronic security will be monitored by Sonitrol Security Systems, Inc (Sonitrol). Kevin Householder of Sonitrol informed DI Colosimo that alarm signals are transmitted from GERXDC to Sonitrol through a static IP, with a cellular backup. Householder stated that both forms of transmission are under constant supervision so that any tampering would be immediately detected. During non-operating hours, if the GERXDC or cage/vault alarm is activated, Sonitrol will contact the local police department (New Sewickley Township Police Department), as well as the GERXDC warehouse call list, which includes GERXDC Loss Prevention personnel, to inform management of the alarm activation. After GERXDC

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management investigates the matter, they will contact Sonitrol to inform them of the result of their investigation.

On December 14, 2015, investigators tested the cage and vault electronic security. This test revealed that an audible alarm could be heard throughout the GERXDC upon unauthorized entry to the cage and vault. The attached results of the test, provided by Sonitrol Security Systems, revealed the security was deemed operational. (**Attachment 5**)

DI Colosimo advised GERXDC management to contact the New Sewickley Police Department regarding the nature of their business. On December 15, 2015, Richard Shaheen, Pharmacy Investigator, informed DI Colosimo via email that he met with the New Sewickley Township Chief of Police and briefed him on various security-related changes at GERXDC. (**Attachment 6**)

#### CAGE SPECIFICATIONS

All Schedule 3-5 controlled substances handled by GERXDC will be stored in a cage measuring 46'5" x 27'8" x 29'1" (height), with the cage walls constructed of #10 gauge steel fabric mounted on 2" diameter posts. (**Attachment 7**) The placement of the posts and the fence openings are compliant with 21 CFR Part 1301.72. An examination of the fencing bolts revealed they were welded/brazed as required by this CFR site. The cage's ceiling and entrance doors are constructed of similar material as the cage's walls. The cage is equipped with self-locking doors; all cage doors are equipped with contact switches. Motion sensors and cameras are strategically positioned to provide adequate coverage.

All elements of this cage appear to meet the requirement specified in 21 CFR 1301.72(b) (4).

#### VAULT SPECIFICATIONS

All Schedule 2 controlled substances handled by GERXDC will be stored in a vault measuring 38'8" x 40'2" x 29'1" (height). (**Attachment 8**) The walls, floor, and ceiling are constructed of 8" of poured concrete reinforced with #4 rebar tied 6 inches on center. The vault is equipped with a self-

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closing, self-locking day gate. The vault door, weighing over 4,000 pounds, is a metal AR5 security vault door manufactured by Overly Door Company, serial number M-5-1054. The vault is equipped with a combination lock. Motion sensors and cameras are strategically positioned in the vault to provide adequate coverage.

Almost all elements of the vault and vault door appeared to meet the requirements specified in 21 CFR 1301.72(a) (3). However, while the vault's day gate was equipped with a contact switch, the vault door was not equipped as such - as required by 21 CFR 1301(a) (3) (v). The vault also was not equipped with either electrical lacing, sensitive ultrasonic equipment, or a sensitive sound accumulator system - as required by 21 CFR 1301(a) (3) (vi).

After the on-site visit, the Pittsburgh D.O. received confirmation that a contact switch was installed on the front door on December 17, 2015. Kevin Householder of Sonitrol informed DI Colosimo that Sonitrol would be installing a sound detection system (**Attachment 9**) within the vault by January 15, 2016 - prior to the firm handling controlled substances.

#### RECEIVING

GERXDC primary suppliers of controlled substances will be MCKESSON DRUG and ANDA DRUG.

All controlled substances delivered to the GERXDC must enter the building through the receiving man-doors #1 and #2, where they will be identified at the point of entry, and transported (by authorized personnel) approximately 100 feet into a secure area within the GERXDC. An operations manager will be responsible for making sure the delivery of controlled substances into the building is secure, and will check the bill of lading to ensure the correct purchase orders have been received. When the shipment has been inspected, the controlled substances will be transported directly to the cage/vault area. Video monitoring records the entire travel path from the receiving dock to the cage/vault.

#### STORAGE

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All controlled substances will be store in a secure cage or vault fully described elsewhere in this report. As outlined in the attached "Inventory Control - Suspected Loss Policy" - all generic controlled substances are cycle counted two times per week, while name brand controlled substances are counted nightly after selection is completed. The attached policy details outline other inventory counts and controls performed at GERXDC.

Inventory discrepancies and reports of used, tampered, or opened products are reported to management for investigation. Management will determine if the loss is significant. Criteria for a significant loss can include, but are not limited to the following:

- Any loss of a controlled substances.
- Discrepancies of five(5) percent or greater of the expected on-hand quantity.
- Repeated discrepancies of the same product within a rolling thirty (30) day period.
- Dollar value losses that exceed five hundred dollars (\$500.00) per occurrence.

Significant losses will be reported to DEA upon discovery.

#### SHIPPING

Upon completion of product selection, completed totes are stacked onto outbound pallets and prepared for shipping. An authorized employee scans each tote label and attaches all tote labels that are on the pallet to a pallet license plate number. The tote count per pallet is then recorded and documentation is printed for shipping verification. Each outgoing shipment will be inspected for identity of the drug product, and the container will be inspected to ensure no damage has occurred. When the outbound carrier arrives at GERXDC, a manager or supervisor will supervise the loading of the pallets. Outbound paperwork will be taken to the loading door, and the manager or supervisor and outbound driver will verify the count of totes on each pallet, as well as the number of pallets to be shipped. Pallets/totes are also inspected at this time for any sign of visual damage or tampering. The driver's and manager's signatures are written on the bill of lading indicating that the counts are correct. If the counts are not correct, the manager will investigate the matter. The

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Warehouse Operations Manager or GERXDC Supervisor will perform and document random audits for outgoing shipments. Video surveillance monitoring will cover the path from the cage/vault to the loading door.

Talon Logistics, the exclusive private carrier for Giant Eagle, will be the primary carrier for GERXDC. Other private carriers used by GERXDC will be Prestige Delivery Systems and Aim Dedicated Logistics. As per 21 CFR 1301.74(e), the firm is responsible for selecting a common or contract carrier which provides adequate security to guard against in-transit losses. HBC has used all three carriers identified above. As noted in the Theft/Loss section of this report, a review of DEA's Theft/Loss database revealed HBC has filed only four DEA Form 106s (Report of Theft or Loss of Controlled Substances) since they were approved by DEA as a distributor in 2009: one loss was attributed to employee pilferage (his employment was terminated); three were described as in-transit losses. HBC appropriately documented on each of the forms security measures they took to prevent or limit future thefts/losses.

### DUE DILIGENCE

Because the supplier (GERXDC) and customers (Giant Eagle Pharmacies) are owned by GIANT EAGLE, INC., GERXDC will have access to customer information that will assist them in enacting the following "Due Diligence" actions:

#### Customer Authentication

To ensure that controlled substances are distributed only to legitimate, properly licensed customers, GERXDC has established a "Customer Authentication" policy (**Attachment 10**). This policy is summarized as follows: The GERXDC only services Giant Eagle Pharmacies which are owned by Giant Eagle, Inc. If, for any reason, a Giant Eagle Pharmacy is not licensed to receive Legend drug products or controlled substances, the GERXDC will no longer service the pharmacy.

GERXDC will maintain copies of all customer licensure - state pharmacy licenses and DEA registration certificates. Licensing information will be

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verified through state agencies websites, as well as the DEA website (www.dea diversion.usdoj). If at any time a pharmacy is not licensed by the DEA and applicable State Board of Pharmacy, no Legend or controlled substances will be sold to them. GERXDC will report to the State Board of Pharmacy, DEA, and the FDA within three (3) business days if they are unable to authenticate a customer.

### Suspicious Orders

As outlined in the attached Order Monitoring Policy, GERXDC has developed an Order Monitoring System (OMS) to assist in detecting suspicious orders placed by any of their customers. (**Attachment 11**) The OMS algorithm generates flags based on monthly thresholds and ordering characteristics specific to the following:

- Pharmacy location
- Controlled Substance/Chemical
- Generic Product Indicator
- National Drug Code
- Week of the month
- Ordering patterns

Flagged controlled substance orders are generated through a daily report. The flagged orders cannot be filled until investigated and resolved by the OMS team, which includes designated individuals from Pharmacy Procurement, Pharmacy Operations, and the Loss Prevention Pharmacy Analyst. Pharmacy Procurement will block the target drug from the identified pharmacy's order during the investigation. Pharmacy Procurement team members can utilize a computer software feature called Supplylogix Pinpoint Order or the drug management function of the pharmacy dispensing system to block the ability of a pharmacy to order the drug or chemical under investigation. GERXDC will quarantine the product from the flagged store's order until the conclusion of the investigation. Orders for flagged stores will be blocked through CSOS until investigated and resolved.

Investigations of flagged orders can include, but are not limited to the following:

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- Purchasing patterns
- Dispensing patterns
- Percentage of controlled substance prescriptions
- Percentage of target controlled substances (e.g. Oxycodone, hydrocodone, buprenorphine)
- Form of payment (Third party or cash)
- Histories and patterns of prescribing physicians
- Interviews of store pharmacists and technicians
- Loss Prevention review of store surveillance video
- Review of Supplylogix Pinpoint Audit (used to identify pharmacies that are at risk for inventory built, I.e. purchases exceed dispensing)
- Review of Supplylogix Pinpoint Monitor (used to identify at risk purchasing patterns)

If the OMS team determines the flagged order is not suspicious, the orders are cleared for distribution by the GERXDC. If the order is deemed to be suspicious, the flagged item remains blocked, and the DEA is notified in writing within one business day of the determination. Law enforcement (DEA/State or local police) may also be notified.

Documentation of the above-described investigations will be retained in readily retrievable form for at least two years. A sample form used to document the investigation is attached to this report. The OMS policy and processes will be reviewed quarterly (for effectiveness and quality) by the OMS Review Committee consisting of several individuals listed in the attached policy.

Richard Shaheen, Pharmacy Investigator, described a few other steps GIANT EAGLE, INC. has taken to limit the potential for diversion occurring within their pharmacies: All Giant Eagle pharmacists have received training on procedures for checking in controlled substance orders; these procedures will assist in the prevention and detection of in-transit losses. While all Giant Eagle pharmacies are required to conduct monthly accountability audits, the pharmacists assigned to complete these audits vary from month to month.

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### APPROVAL OF APPLICATION

On January 8, 2016, with the approval of GS Kurt Dittmer, the GERXDC application for registration as a distributor was approved; GERXDC was assigned DEA Number RG0491047.

### ATTACHMENTS

1. Certificate of Registration from PA Department of Health
2. Sign-in Sheet
3. CFR sites
4. Correspondence from Giant Eagle legal counsel
5. Security test results
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